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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,730	06/23/2006	Tsuneo Yasuma	2006_0958A	6117

513 7590 02/23/2009

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EXAMINER	
COPPINS, JANET L	

ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
02/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,730	YASUMA ET AL.	
	Examiner	Art Unit	
	JANET L. COPPINS	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,17 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-11 and 13* is/are allowed.

6)☒ Claim(s) *17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-11, 13, 17 and 18 are currently pending in the instant application.

Information Disclosure Statement

2. Applicants' Informational Disclosure Statement (IDS), submitted December 12, 2008, has been considered by the Examiner. Please refer to the signed copy of Applicants' PTO-1449 form, submitted herewith.

Response to Amendment

3. Applicants' Amendment and Response, submitted September 29, 2008, has been reviewed by the Examiner and entered of record in the file. Accordingly, claims 12 and 14 have been cancelled, and claims 13 and 17 have been amended.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 17 previously rejected under 35 U.S.C. 112, first paragraph, as not being enabled for being a reach-through claim. Applicants have inserted specific diseases to be treated into the claim, however the claim is newly rejected, please refer to the 35 USC 112, second paragraph rejections, below.

Claim 18 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds that bind GPR40 does not reasonably provide enablement for the prophylaxis of any diseases. The term "prophylaxis" includes both treatment and prevention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention in claim 18 is a method for the treatment or prophylaxis of diabetes. Even if the patient has a genetic predisposition to the selected identified disease, one is still treating the individual patient, and not preventing. It has not been shown in the specification that the "**prophylaxis**" of such disease is accepted in the art as being predictive of the utility alleged, especially when absent of pharmacological data.

The state of the prior art

Regarding the "prophylaxis" or prevention of diabetes by use of a compound of claim 1, the Examiner was not able to locate existing or prospective clinical studies in the art demonstrating blanket "prevention" of any type of diabetes, as recited in claim 18, so there were no benchmarks against which to compare the efficacy of the claimed chemical compound of claim 1 for the absolute prevention of diabetes. Therefore, the state of the art is limited to treatment of said diseases and not the "prophylaxis" or prevention of diabetes.

The level of skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

The predictability or lack thereof in the art

Because of high level of unpredictability associated with **"prevention"** of a disease, a greater amount of evidentiary support is needed to fully satisfy the requirement of 35 U.S.C 112, first paragraph. It is noted that pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present

The specification fails to disclose methods of treating any disease using the compounds described in the specification. The compounds that are disclosed in the specification, which have data regarding the claimed compounds' affinity of the GPR40 receptor, have no pharmacological

data regarding the treatment or prevention of any said diseases. The specification is short of any working data (animal models or *in vivo* testing) in regards to the prevention of said diseases. Merely stating that the instant compounds are preventable against, for example diabetes or insulin resistance, does not establish usefulness of the invention absent art-recognized correlation between such tests and the ultimate use.

The presence or absence of working examples

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that compounds fall within the scope of a claim will posses the alleged activity. See *In re Riat* et al. (CCPA 1964) 327 F2d 685, 140USPQ 471; *In re Barr* et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724. The instant specification at most only provides examples of intermediates and processes of preparation. Applicants describe a single *in vitro* assay detailing the instant compounds' ability to bind GPR40 in human CHO cell lines, please refer to EC50 values on page 140. No examples have been set forth describing the administration of the instant claimed compounds for treating or preventing any diseases.

The quantity of experimentation needed

Based on the unpredictable nature of the invention and the state of the prior art and the breadth of the claims, one of ordinary skill in the art would be burdened with undue "experimentation study" to determine whether the claimed compounds would prevent the claimed diseases. *Genentech Inc. v. Novo Nordisk* A/S (CAFC) 42 USPQ2d 1001 , states that, "a patent is not a hunting license. It is not a reward for research, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *In re Wands* factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which compounds would prevent diabetes by the method encompassed in the instant claims, with no assurance of success.

It is suggested to delete the terms "prophylaxis or" to overcome the rejection.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 13 and 14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 has been amended, and claim 14 has been cancelled, therefore the indefiniteness rejections have been overcome.

However, please refer to the following new claim rejection:

Claim 17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 is indefinite since it is unclear as to the scope embraced by the term "modulating." The term "modulating" encompasses both inhibition and enhancement. While a compound can either inhibit or enhance physiological function, it can not perform opposite activity simultaneously (see CA135:317215; CA142:461958).

Furthermore, the term "modulating" denotes an increase or decrease in cell mass; while proliferation is an increase in cell mass, thus the two terms together are self-conflicting and therefore indefinite. Therefore, the term renders the scope of the claims indefinite.

Conclusion

8. In conclusion, claims 1-14, 17 and 18 are currently pending in the application. Claims 1-11 and 13 appear allowable over the prior art, claims 17 and 18 are rejected.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. COPPINS whose telephone number is (571)272-0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI-TSANG SHIAO /

Janet L. Coppins
January 26, 2009

REI-TSANG SHIAO
Primary Examiner, Art Unit 1626